K131538

510(k) Summary

AUG 8 2013

Date Prepared:	May 27, 2013
Submitter Contact:	Dale Mitchell Captiva Spine 967 Alternate A1A #1 Jupiter, FL 33477 877-772-5571 866-318-3224
Regulatory Contact:	Rich Jansen, Pharm. D. Silver Pine Consulting, LLC 612-281-5505 richj@s-pineconsulting.com
Trade Name:	CapLOX II/TowerLOX Pedicle Screw System
Product Class:	Class II
Classification:	888.3070 Pedicle Screw Spinal System 888.3050 Spinal Interlaminal Fixation Orthosis
Product Codes:	MNI, MNH
Panel Code:	87

Reason for this Submission: This Special 510(k) involves several changes to the previously cleared TowerLOX System that allow for:

1. Adding several new rod lengths
2. New instrumentation
3. Adding new cross connector sizes

Indications for Use:

The CapLOX II/TowerLOX Pedicle Screw System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CapLOX II/TowerLOX Pedicle Screw System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

Device Descriptions:

The CapLOX II/TowerLOX Pedicle Screw System is an implant device made from a titanium alloy TI 6Al 4V-ELI. It is to be implanted from the posterior approach. The screws are available in diameters from 4.9-8.0mm and in lengths from 30-100mm. Rods are available in 5.5mm diameter in lengths from 30-600mm and in an array of configurations including, straight and

pre-lordosed configurations. The system includes set screws, pedicle screws, and rods along with the associated instrumentation to complete the procedure and implant construct.

Predicate Device(s):
The CapLOX II/TowerLOX Pedicle Screw System is substantially equivalent to the previously cleared CapLOX II/TowerLOX pedicle screw system found in K122332, the CapLOX II Pedicle Screw System (K120292) and the Depuy Viper Spinal System (K121020).

Performance Standards:
Based on the risk analysis for the proposed changes, no new performance testing is required.

Conclusion:
Captiva Spine concludes that these changes to the CapLOX II/TowerLOX Pedicle Screw System is substantially equivalent to the predicate with the same name and raises no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 8, 2013

Captiva Spine
% Silver Pine Consulting, LLC
Rich Jansen, Pharm.D.
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K131538
Trade/Device Name: CapLOX II/TowerLOX Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: July 8, 2013
Received: July 9, 2013

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin L. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131538

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Prescription Use ___V____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices